

METHOD FOR PURIFYING ANTIBODIES

SUMMARY

The National Cancer Institute seeks partners to license or co-develop an FDA/EMA-approved Chemistry, Manufacturing and Controls (CMC) large-scale manufacturing process for the production of GMP-grade chimeric antibodies.

REFERENCE NUMBER

E-291-2014

PRODUCT TYPE

- Therapeutics

KEYWORDS

- GMP Manufacturing, Chimeric Monoclonal Antibodies, Unituxin™, Neuroblastoma

COLLABORATION OPPORTUNITY

This invention is available for licensing and co-development.

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DESCRIPTION OF TECHNOLOGY

This technology is a method for purifying a biologic composition, comprising diafiltering the biologic composition into a composition comprising phosphate buffered saline (PBS) to obtain a purified composition. The method is particularly useful for removing one or more impurities from the biologic composition, such as bis(2-hydroxyethyl)amino-tris(hydroxymethyl)methane (Bis-tris). The technology is directed to large scale manufacturing of Chimeric 14.18 (Ch14.18) monoclonal antibodies. Ch14.18 is an anti-GD2 monoclonal antibody and has been described in Gillies *et al.*, *Journal of Immunological Methods* 125:191-202 (1989) and US Patent 5,541,087.

FDA/EMA approved Chemistry, Manufacturing and Controls (CMC) large scale manufacturing to produce GMP grade chimeric antibodies.

POTENTIAL COMMERCIAL APPLICATIONS

- Large scale manufacturing of chimeric monoclonal antibodies

COMPETITIVE ADVANTAGES

- Cost effective means of removing impurities to produce GMP grade chimeric antibodies for regulatory approval.

INVENTOR(S)

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DEVELOPMENT STAGE

- Clinical

PUBLICATIONS

1. [FDA published document](#)
2. [US Food and Drug Administration. FDA approves first therapy for high-risk neuroblastoma.](#)
3. [WO2016015048](#) METHOD FOR PURIFYING ANTIBODIES

PATENT STATUS

- **U.S. Filed:** US Provisional Patent App. No. 62/028,994, filed July 25, 2014
- **U.S. Filed:** US Patent App. No. 14/809,211, filed July 25, 2015
- **Foreign Filed:** International Patent App. No. PCT/US2015/042241, filed July 27, 2015

THERAPEUTIC AREA

- Cancer/Neoplasm